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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,024	12/02/2003	Manesh Dixit	141-239A	2662

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/726,024	DIXIT ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/28/2008 has been entered.

Response to Arguments

Applicant's arguments over the 35 USC 103 rejection over Mehta in view of Mulye and Beiman have been fully considered. In particular, Applicant's argue that an enteric coated methylphenidate tablet that exhibits the recited dissolution profile in pH 7.5 is not disclosed or suggested by the references of record. Applicants assert that the ammonio methacrylate copolymers taught by Mehta are not enteric polymers and Mehta fails to disclose the use of a compressed admixture of methylphenidate and a hydrogel polymer to control the release of methylphenidate from the core. Applicants argue that the Mulye reference fails to suggest the controlled release methylphenidate tablet recited in the current claims and Mulye teaches multiparticulate dosage forms, but not methylphenidate dosage forms, wherein the release of the drug is controlled by a coating comprising an enteric polymer and water insoluble polymer. Applicants further argue that Beiman teaches multiparticulate dosage forms but fails to mention

methylphenidate. Applicants argue that one would conclude that the pellets of Beiman would rapidly release in a high pH media similar to the Mulye pellets because of the structural similarities between the two references.

In response to the above arguments concerning Mehta, it is noted that the Mehta reference was not used to teach enteric polymers and there was no reference to ammonio methacrylate copolymers in the rejection. Further, it is noted that Mehta teaches a preparation in the invention in which a 10 percent solution of hydroxylpropyl methylcellulose (HPMC) was mixed in with a solution of methylphenidate of which was then coated with a sealant (Example 1), which reads on an admixture of methylphenidate and a hydrogel polymer in the core. Further, it is recognized that Mulye teaches a pharmaceutical composition comprising a core element comprising a medicament and a coating comprised of an enteric polymer and a water insoluble polymer. It is further noted that the present claims contain "comprising" and "consisting essentially of" language are open-ended (see further discussion of this below) and do not exclude other elements. Applicant points to the release profile in Col. 16 and the release rates in pH 7.4. The claims are drawn to a controlled release methylphenidate tablet comprised of the elements of (A), (B) and (C) and the dissolution profile given in claim 1 is not afforded any patentable weight as will be discussed further below. Accordingly, Mulye is used for the teaching of controlled release pharmaceutical compositions that comprise an enteric polymer. Further, it is noted that the Beiman reference was used for the teaching of the enteric polymer containing processing aids to aid in delayed release of the drug and not for the limitation of teaching methylphenidate.

Further, one would not necessarily conclude that the pellets of Beiman would rapidly release in a high pH media because it is taught in Col. 9, lines 21-38, enteric polymers such as Eudragit S are slowly soluble in buffer solutions above a pH of 7.0.

Due to Applicant's amendments, the following modified rejections are being given below.

Absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" language of the instant claims will be construed as equivalent to "comprising". See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al. (U.S. Patent 5,837,284) in view of Mulye (U.S. Patent 6,475,493) and Beiman et al. (U.S. Patent 6,312,728).

Mehta et al. teach an improved dosing of methylphenidate hydrochloride whereby two time-separated doses are provided via a single dosage unit, in which a first group of particles provides an immediate dose of methylphenidate in an amount from about 2% to about 99% by weight and a second group of particles provides a second dose of methylphenidate in an amount from about 2% to about 75% with a binder (Col. 1, lines 13-17, Col. 3, lines 41-43, Col. 4, lines 12-14). Mehta et al. further teach a coating that delays the release of the methylphenidate (Col. 4, lines 32-36). The dosage unit is comprised of hydroxypropyl methylcellulose in an amount of 10 percent (Col. 10, lines 42-50). Mehta et al. further teach that the maximum concentration of the first dose occurs from about 1 hour to about 3 hours after ingestion, which is followed by a period when no drug is released which lasts approximately 2-6 hours, and the second dose is released about 6 hours following administration (Col. 5, lines 37-51 and Fig. 2).

Mehta et al. does not teach a diluent in the core, processing aids, that the coating is specifically made up of enteric coating polymers, a maximum plasma concentration and AUC_{0-24}.

Mulye teaches a coating composition in a controlled release pharmaceutical composition which comprises an enteric polymer (Col. 4, lines 59-62). Active medications that can be used in the composition include methylphenidate (Col. 9, line 42). The compositions contain lactose in an amount of 2 to 70% (Col. 11, line 41) as well as colloidal silicon dioxide and magnesium stearate (Col.8, lines 4-5). Enteric polymers are present, including methacrylic acid copolymer (Col. 6, lines 28-29) and zein (Col. 12, line 22).

Similar to the teachings of Mehta et al. and Mulye, Beimen et al. teach oral dosage delivery systems comprised of a core comprising a therapeutic agent, an enteric polymer coating over said core, a coating of said therapeutic agent over enteric polymer coat and a protective coating (Col. 7, lines 5-19). Beimen et al. teach that the enteric polymer coating may also contain processing aids (Col. 8, lines 8-10). The most preferred enteric coating is Eudragit L30D-55, which is a methacrylic acid copolymer, and is applied as a 45-55 % weight aqueous solution (Col. 9, lines 11-18).

Furthermore, it is obvious to vary and/or optimize the weight of each ingredient in the controlled release formulation according to the guidance provided by Mehta et al. and Mulye, to ensure that the proper amount of drug is released at the designated time interval. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The dissolution profile, maximum plasma concentration and AUC of the controlled release methylphenidate tablet as claimed in claims 30-32, 43-47 and 49-54 is considered a property of the controlled release tablet of the invention. If the prior art has the same components, then the properties of the composition will necessarily follow. Because the combination of the prior art renders the claimed controlled release formulation obvious, the dissolution profile would be a property of the formulation. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Mehta et al, which teach a composition for the improved dosing of methylphenidate, with Mulye and Beiman et al., which teach a controlled release pharmaceutical composition that comprises an enteric polymer that aids in delayed release of the drug. One having ordinary skill in the art would have been motivated to combine the teachings of Mehta et al. with Mulye and Beiman et al. to formulate a controlled release composition of methylphenidate to reduce abuse potential and for better patient compliance to treat nervous system disorders (as taught by Mehta et al.; Col. 1, lines 26-32).

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617